Table of Contents

Acknowledgements
Introduction1-10
Overview of Document1-3
Section 1
Estimating the number of culture-confirmed cases of campylobacteriosis1.1 - 1.11
Section 2.
Estimate of the total number of Campylobacteriosis Cases
Section 3
Estimate of expected number of people with FQ resistant infections
Section 4.
Estimating year's consumption of domestically reared chickens
Section 5.
Using the model to manage risk
Appendix A. Distributions used in uncertainty analysis
Appendix B. Mean values of the confidence limitsB-10 - B-11
Appendix C. Prioritized List of Assumptions and Limitations of Data
References

Acknowledgements

In the preparation of this draft document we have received assistance and comments from numerous individuals and agencies and it is appropriate at this time to acknowledge their generous contributions. Specific acknowledgements, recognizing individual contributions, will appear in the final draft of this document. The following agencies and institutions contributed time and expertise in analyzing and providing data, providing expert opinion or commenting on and reviewing the document.

The Centers for Disease Control and Prevention
USDA- Agricultural Research Service
USDA-Food Safety Inspection Service
USDA-Economic Research Service
National Chicken Council
U.S. Census Bureau
University of Pennsylvania Medical Center

Individuals involved in the preparation of this risk assessment:

Project Manager Sharon Thompson

Project Coordinator
Margaret Miller

Risk Modeler
David Vose
David Vose Consultancy Ltd.
La Coutancie
24320 Nanteuil-Auriac de Bourzac
Dordogne, France

Writing, Data Collection and Analysis
Mary Bartholomew, Statistics
Katherine Hollinger, Epidemiologist

Information Specialist and Support
Deborah Brooks
Kathy Hemming

Revision

At the FDA Center for Veterinary Medicine Workshop on Risk Assessment and the Establishment of Thresholds held in Rockville MD, on December 9-10, 1999 CVM stated that a revised version of the Risk Assessment would be placed on the Web to improve flow and consistency of the document.

A number of improvements to the wording and structure have been made to improve consistency of language and notation. Other minor changes were made to correct typographical errors and improve clarity for readers. Additional changes are listed in the bullets below:

- A section titled "Using the Model to Manage the Human Health Impact" was added to the Introduction.
- A footnote describing the denominator for the proportion of physicians requesting stools from patients with bloody diarrhea was included in Section 2.2. The model will be updated with receipt of additional data from the physician's survey increasing the denominator from 18 to 180. The larger data set will be used in the final report and will have little impact on the results except to slightly decrease model output uncertainty.
- Section 3.5 A footnote describes a recognized logical inconsistency in this parameter estimate (p_{rh}) that has not been corrected in this model. We have removed cases of campylobacteriosis attributable to sources other than chicken. Because resistance was predominantly attributed to chickens, after removal of travelers and prior fluoroquinolone use, the remaining "chicken associated cases" should reflect the level of resistance restricted to the chicken associated cases. This correction will be made in the final revision.

Interested persons should submit written comments on the draft risk assessment to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Comments should be identified with Docket Number 98D-0969. The deadline for receipt of comments has been extended to February 24, 2000.

Ouestions about the risk assessment may be addressed to:

Dr. Nicholas Weber, FDA/Center for Veterinary Medicine, 7500 Standish Place, HFV-150, Rockville, MD 20855, 301-827-6986 e-mail nweber@cvm.fda.gov